



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,420	06/08/2006	Michael Pieroth	00435P0012WOUS	5302

30008 7590 12/29/2009
GUDRUN E. HUCKETT DRAUDT
SCHUBERTSTR. 15A
WUPPERTAL, 42289
GERMANY

EXAMINER

SOROUGH, LAYLA

ART UNIT	PAPER NUMBER
----------	--------------

1627

MAIL DATE	DELIVERY MODE
-----------	---------------

12/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,420	Applicant(s) PIEROTH ET AL.	
	Examiner LAYLA SOROUGH	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-66 is/are pending in the application.
- 4a) Of the above claim(s) 63-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-62, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/06; 6/8/06, 12/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Office Action is in response to the Applicant's reply filed October 21, 2009 to the restriction requirement made on September 30, 2009.

Applicant's election without traverse of Group I claims 54-62 and 65-66, in the reply filed on filed October 21, 2009 is acknowledged.

The requirement is deemed proper and is therefore made **FINAL**. Claims 54-66 are pending. The claims 63-64 are withdrawn. Claims 54-62 and 65-66 are herein acted on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-60 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Floyd et al. (US 5942510) in view of Smith et al. (US 6194000 B1).

Floyd et al. teaches a lamotrigine lyophilized formulation and uses the methanesulphonate salt form. The formulations can be reconstituted in a volume of a solution (col 2 lines 46-50). The lamotrigine mesylate is in an amount of 250 mg (col 2 lines 63-64). The lyophilized formulation further consist of bulking agent selected from mannitol (mannite) and glycine in 197-470 mg (col 3 lines 7-13). The amount of cake forming agent falls within the claimed range (see

Art Unit: 1627

Example). Mannitol is particularly useful for its cake-forming properties (col 4 line 61).

The reference fails to teach the specific compound flupritine and is silent to the amount of the salt.

Smith et al. is solely used to show that lamotrigine and flupritine are both NMDA receptor antagonist morphinans (see claim 31).

Therefore, it would be obvious to one of ordinary skill in the art to interchange the use of lamotrigine and flupritine. The motivation comes from the teaching of Smith et al. that lamotrigine and flupritine are both NMDA receptor antagonist morphinans. Additionally, the determination of optimal or workable concentrations and/or ratios of ingredients by routine experimentation is obvious absent showing of criticality of the claimed concentrations and ratios. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavoring and consistency properties of the composition.

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Floyd et al. (US 5942510) in view of Smith et al. (US 6194000 B1), as applied to claims 54-60 and 65-66, and further in view of Remon (US 6010719 A).

The references fail to teach an antioxidant such as ascorbic acid.

Remon teaches additives of the lyophilized formulation comprise an antioxidant such as ascorbic acid.

Therefore, it would be obvious to one of ordinary skill in the art to incorporate the additive ascorbic acid. The motivation comes from the teaching

Art Unit: 1627

of Remon that the lyophilized formulation comprise an antioxidant such as ascorbic acid. Hence, a skilled artisan would have had reasonable expectation of successfully producing a composition that with antioxidant properties. Additionally, the determination of optimal or workable concentrations and/or ratios of ingredients by routine experimentation is obvious absent showing of criticality of the claimed concentrations and ratios. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavoring and consistency properties of the composition.

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Floyd et al. (US 5942510) in view of Smith et al. (US 6194000 B1), as applied to claims 54-60 and 65-66, and further in view of Shima et al. (US 4767874).

The references fail to teach an detergent such as Polyvinylpyrrolidine.

Shima et al. teaches freeze-dried formulations stabilizers such as Polyvinylpyrrolidine in 0.05-5 pts. wt. of stabilizer to 1 pt. wt. of (I) of the composition.

Therefore, it would be obvious to one of ordinary skill in the art to incorporate the stabilizers Polyvinylpyrrolidine. The motivation comes from the teaching of Shima that the freeze-dried formulations stabilizers such as Polyvinylpyrrolidine in 0.05-5 pts. wt. of stabilizer to 1 pt. wt. of (I) of the composition. Hence, a skilled artisan would have had reasonable expectation of successfully producing a composition that with stabilizing properties.

Additionally, the determination of optimal or workable concentrations and/or

Art Unit: 1627

ratios of ingredients by routine experimentation is obvious absent showing of criticality of the claimed concentrations and ratios. One having ordinary skill in the art would have been motivated to do this to obtain the desired flavoring and consistency properties of the composition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

